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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,101	02/19/2002	Klaus Gregorius Nielsen	674542-2003	7906
20999	7590	11/13/2003	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			TURNER, SHARON L	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,101

Applicant(s)

NIELSEN ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-19-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Election/Restriction

1. Claims 1-38 are pending.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25 in part drawn to an immunogen, classified for example in class 536, subclass 23.1.
 - II. Claims 26-38 in part drawn to a method for immunizing an animal, classified for example in class 536, subclass 23.1.
3. The inventions are distinct, each from the other because of the following reasons:
4. The inventions of Group I are related as products. The products are distinct each from the other as they exhibit divergent structure and function and are capable of different use.
5. Inventions I-II are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the immunogens can be practiced with alternative immunogens and the products as claimed can be used alternatively in a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
7. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as

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indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

Mechanisms of coupling selected from a) a bond cleavable by a peptidase, b) an amide bond, c) a peptide bond, d)

Polyhydroxypolymer carriers selected from a polyhydroxypolymer that is a) substantially free of amino acid residues, b) water soluble, c) water insoluble, d) naturally occurring, e) synthetic, is a polysaccharide selected from f) acetan, g) amylopectin, h) gum agar-agar, i) agarose, j) alginates, k) gum Arabic, l) carageenan, m) cellulose, n) cyclodextrins, o) dextran, p) furcellaran, q) galactomannan, r) gelatin, s) ghatti, t) glucan, u) glycogen, v) guar, w) karaya, x) konjac/A, y) locust bean gum, z) mannan, aa) pectin, ab) psyllium, ac) pullulan, ad) starch, ae) tamarine, af) tragacanth, ag) xanthan, ah) xylan, ai) xyloglucan, is aj) dextran, is a highly branched ak) poly(ethyleneimine) (PEI), al) tetrathienylene vinylene, am) Kevlar (long chains of poly-paraphenyl terephthalamide), an) poly(urethanes), ao) Poly(siloxanes), ap) polydimethylsiloxane, aq) silicone, ar) Poly(methylmethacrylate) (PMMA), as) Poly(vinyl alcohol), at) Poly(vinyl pyrrolidone), au) Poly(2-hydroxy ethyl methacrylate), av) Poly(N-vinyl pyrrolidone), aw)

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Poly(vinyl alcohol), ax) Poly(acrylic acid), ax) Polytetrafluoroethylene (PTFE), ay) Polyacrylamide, az) Poly(ethylene-co-vinyl acetate), ba) Poly(ethylene glycol) and derivatives, bb) Poly(methacrylic acid), bc) Polylactides (PLA), bd) Polyglycolides (PGA), be) Poly(lactide-co-glycolides) (PLGA), bf) Polyanhydrides, bg) Polyorthoesters, is activated with functional groups selected from bh) tresyl (trifluoroethylsulphonyl), bi) maleimido, bj) p-nitrophenyl chloroformate, and bk) tosyl (p-toluenesulfonyl).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of coupling mechanism and polyhydroxypolymer for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission

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may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.
November 12, 2003